UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,758	06/10/2005	Hiromu Habashita	Q88484	6854

65565 7590 03/27/2008

SUGHRUE-265550
2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
JARRELL, NOBLE E	
ART UNIT	PAPER NUMBER
1624	
MAIL DATE	DELIVERY MODE
03/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,758	HABASHITA ET AL.	
	Examiner	Art Unit	
	Noble Jarrell	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I (ring A is azepane and ring B is pyrimidine) in the reply filed on 12/28/2007 is acknowledged.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The PCT application which this application relies on for priority is not published in English, and therefore does not decide the priority date of the instant application. The priority date of the instant application as it stands currently is June 10, 2005, because the PCT is published in Japanese, not English.

Specification

3. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

4. The attempt to incorporate subject matter into this application by reference to claim 28 is ineffective because applicants cite various WO applications for examples of CCR2, CCR3, CCR4, and CCR5 antagonists (page 70 of specification).

Claim Objections

5. Claims 1-8, 10-18, 10-31, and 33-34 are objected to because of the following informalities: the claims contain non-elected subject material. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-31 and 33-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for salts of formula I, does not reasonably provide enablement for *N*-oxides, solvates and prodrugs of formula I. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are enabled for salts of formula I. In the art, it is recognized that a tertiary amino group (the nitrogen of the azepane is a tertiary amino group) can from a salt with an acid or base. Applicants have not shown how to and do not show any examples of *N*-oxides, as well as how to prepare prodrugs and solvates of formula I. Vippagunta (*Advanced Drug Delivery Reviews*, **2001**, *48*, 3-26) shows that solvate formation is unpredictable within a series of related molecules because each molecule responds uniquely to solvate formation (page 18, section 3.4). Jantzen and Robinson (*Modern* Pharmaceutics, 1996, page 596) show that identification of an optimum substituent for a parent compound to become a prodrug requires undue experimentation. Once a prodrug is formed, extensive safety and efficacy testing is required. Hence, the formation of *N*-oxides, prodrugs, and solvates in not enabled.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to compounds composed of at least two rings and a hydrocarbon group attached to the second ring.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Compounds of formula I are known in the art (see 102 rejections). Solvate formation is unpredictable and prodrug identification requires undue experimentation.

(5) The relative skill of those in the art:

One of ordinary skill in the art is familiar with the synthetic procedures used in the specification.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for preparation of salts of compounds of formula I, but there is no guidance for the formation of *N*-oxides, solvates, and prodrugs of compounds of formula I.

(8) The quantity of experimentation necessary:

Jantzen and Robinson show that extensive safety and efficacy testing is required for a prodrug.

Considering the state of the art as discussed by the references above, particularly with regards to claims 1-31 and 33-34 and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

8. Claims 33-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of disorders listed in claims 33 and 34, does not reasonably provide enablement for prevention of disorders listed in claims 33-34. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are not entitled to prevention of disorders listed in claims 33-34. Cancer is more than 100 different diseases ("Definition of cancer", http://www.medterms.com/script/main/art.asp?articlekey=2580, accessed January 27, 2007), and prevention for one type of cancer is not necessarily prevention for another type of cancer. In addition, it is shown that cancer in general is not curable ("There is no cure for cancer", http://www.fwhc.org/health/nocure.htm, accessed February 20, 2008). HIV is not preventable through administration of drugs ("Overview of HIV prevention", http://www.avert.org/prevent-hiv.htm, accessed February 20, 2008). In addition, simultaneous prevention and treatment is impossible. This phenomenon is impossible because if a subject has a disease, the disease cannot be prevented. If a subject does not have a disease, it can only be prevented, but not treated.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to the treatment and/or prevention of various disorders that may be linked with chemokine receptors.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Since cancer is more than 100 different diseases, it is not preventable. HIV is not preventable. Fuijii et al. (*Expert Opinion in Investigational Drugs*, **2003**, *12(2)*, 185-195) show that CXCR4 antagonism is associated with X4-HIV-1.

(5) The relative skill of those in the art:

One of ordinary skill in the art is familiar with the assay described on page 388.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for the treatment of HIV.

However, the specification does not provide guidance for the prevention of any disease in claim 33 or 34.

(8) The quantity of experimentation necessary:

9. Considering the state of the art as discussed by the references above, particularly with regards to claims 33-34 and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

10. Claims 1-8, 10-31, and 33-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no discernible core for formulae I, I-1, I-2, I-3, I-B, and II. The definitions of A and B in each of the formulae are so broad that defining a core is difficult. In an analysis of formula I, for example, ring A is any heterocyclic ring with at least one nitrogen, ring B is a carbocyclic or heterocyclic ring, and Y is any hydrocarbon group. In addition, each of these groups is optionally substituted. What substituents are attached to these groups? In the other formulae, only one of the rings is defined, and that rings only defines one-third of the compound.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is

> claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case is discussed below.

In the instant case, the claims are drawn to compounds with at least two rings, one heterocyclic and the other ring carbocyclic.

(1) Level of skill and knowledge in the art:
Compounds of formula I are known in the art (see 102 rejections).

(2) Partial structure:
Based on an analysis of formula I, there is no partial structure because each of the meanings for variables A, B and Y are so broad.

(3) Physical and/or chemical properties and (4) Functional characteristics:
Applicants show that prepared compounds can be used in in vitro assays.

(5) Method of making the claimed invention:
Applicants show different methods of producing compounds disclosed in the specification.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) claims 1-8 and 10-34 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any compound comprising a nitrogen containing heterocycle, a carbocycle or heterocycle, and a hydrocarbon

group. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of claim 9 and compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-31 and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the terms "an amino group which may be protected", "a hydroxyl group which may be protected", and "a mercapto group which may be protected" are indefinite. Greene et al. (*Protective Groups in Organic Synthesis*, **1999**, pages 17-23, 454-458, and 494-503) list various protecting groups for the hydroxyl, thiol, and amino groups, respectively. What groups are attached to rings A and B, and variable Y? Claim 34 is

indefinite as to what specific disorders are meant by each of the terms besides HIV infection. The terms Inflammatory diseases, immune diseases, allergic diseases, infectious diseases, diseases accompanied with HIV infection, psychoneurotic diseases, cerebral disease, cardiovascular disease, metabolic diseases, and cancerous diseases are all each indefinite ("Cardiovascular diseases", http://www.nlm.nih.gov/cgi/mesh/2008/MB_cgi, accessed February 20, 2008; "Metabolic diseases", http://www.nlm.nih.gov/cgi/mesh/2008/MB_cgi, accessed February 20, 2008; “Neoplasms", http://www.nlm.nih.gov/cgi/mesh/2008/MB_cgi, accessed February 20, 2008; "Inflammation"", http://www.nlm.nih.gov/cgi/mesh/2008/MB_cgi, accessed February 20, 2008; “hypersensitivity:, http://www.nlm.nih.gov/cgi/mesh/2008/MB_cgi, accessed February 20, 2008; "Infection", http://www.nlm.nih.gov/cgi/mesh/2008/MB_cgi, accessed February 20, 2008; "Cerebral arterial disease", http://www.nlm.nih.gov/cgi/mesh/2008/MB_cgi?mode=&index=2433&field=all&HM=&II=&PA=&form=&input=, accessed February 20, 2008).

13. Claims 8, 17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the meanings of variables L and Q. Since claim 8 is independent of claim 7, it cannot refer back to meanings of these variables in claim 7. Claims 17 and 19 refer back to claim 7 for meanings of variables. However, these claims are independent of claim 7, and the meanings of each of the variables must be recited in the claims.

Claim(s) 33 is unclear as to its intended scope. Such claim language reciting inhibitory activity is generally used to denote a causative factor in determining the process by which a particular disease occurs. Determining whether a given disease responds or not to inhibition of “CXCR4” involves much experimentation since a negative response from one patient does not

mean the drug isn't useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular compound is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, paragraph two, is whether applicants have clearly defined "their" invention not what may be discovered by future research as this type of claim language clearly requires.

14. Claims 5 and 6 recite variable J. There is insufficient antecedent basis for this limitation in the claim. Since each claim is dependent on claim 1, and variable J is not present in claim 1, a lack of antecedent basis is present.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-3, 10-18, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnaiz et al. (WO9837079, August 27, 1998). Arnaiz et al. teach compounds listed from page 210, line 23 to page 212, line 214, except for the compound on page 241, lines 7-8. Each of these compounds anticipates formula I because the core is an azepane ring connected to a pyrimidine at the 4-position of the pyrimidine ring (through the 1-position of the azepane ring). The pyrimidine ring is substituted at its 6-position by a methyl group in each of the compounds, and an imidazole ring is attached to the 2-position of the pyrimidine ring. Compositions of these

compounds are taught on page 52, lines 3-24. Claims 11-16 are anticipated because they are each composition claims, and the intended use has no patentable weight.

17. Claims 1-3, 7-8, 10-16, and 19-27 rejected under 35 U.S.C. 102(a) as being anticipated by Nuss et al. (WO2004048365, published June 10, 2004). Nuss et al. teach compound 50 (page 70). This compound anticipates compounds of claims 1-3 and 7-8 because ring A is azepane and ring B is a substituted pyrimidine. The pyrimidine is substituted at its 4-position by an NH-benzimidazole group and 3-hydroxy-phenyl group at its 6-position. Compositions are taught from page 45, line 25 to page 50, line 6. In claims 7 and 8, ring J is benzimidazole, a 9-membered heterocyclic ring substituted by two nitrogen atoms. Claims 11-16 are anticipated because they are composition claims, and the intended use has no patentable weight. Claims 20-27 are anticipated because they are compound claims, and the intended use has no patentable weight in a compound claim.

18. Claims 1-3 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Postovskii et al. (*Doklady Akademii Nauk SSSR*, **1966**, *166(5)*, 1136-39, please see STN search report). Postovskii et al. teach a structure with RN 5767-37-3. This structure anticipates formula I because it is a resonance structure of a compound of formula I where ring A is azepane and ring B is pyrimidine. When the pyrimidine is fully aromatic, it is substituted at its 4-position by a $NHNH_2$ group. Since the pyrimidine is substituted by an amino group, this structure reads on claim 1.

19. Claims 1-6, 10-18, 25-27, 31, 33, and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Nishizawa et al. (WO2004080966, published September 23, 2004). Nishizawa et al. teach compound 41 (page 278). This compound anticipated claims 1-6 and 17-18 because ring A is azepane, Ring B is pyrimidine, and Y is NH(piperidine-4-CH_2-phenyl-4-O-4-$NHSO_2$Me-phenyl. Compositions are taught on pages 283-385. Claims 11-16 and 25-27 are anticipated

because the compounds are CXCR4 antagonists. Claims 31, 33, and 34 are anticipated because the compound is a CXCR4 antagonist, and is being used to treat various diseases (see abstract).

Allowable Subject Matter

20. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner
Art Unit 1624